

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, drawn to forward and reverse primer for amplifying HPV.

Group II, claim(s) 29-30, drawn to an array having at least one probe to the HPV E1 gene.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: as an initial matter, the International Preliminary Report on Patentability held that unity of invention was lacking between the primers represented by SEQ ID NOs 1-7 and the probes represented by SEQ ID NOs 19, 32, 41, 44, 48, 84 and 117-135, stating: "It is already known that the E1 region is preserved and is therefore suitable for HPV diagnosis, and therefore any inventions based on these SEQ IDs are separate inventions."

Moreover, Thunnissen et al (WO 03/87829, prior art of record) teach degenerate primer pairs for amplifying the HPV E1 gene (relevant to Group I above; see page 4, lines 1-6) and arrays with HPV type-specific probes to the E1 amplicons (relevant to Group II above; see page 7, lines 12-15 and page 12, lines 11-17). Hence, there is no special technical feature that ties Groups I and II, as the primer sequences of Group I are structurally distinct from the probe sequences of Group II.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Species 1-128 correspond to SEQ ID NOs 8-135 of Group II, respectively.

If Group II is elected, Applicant is required, in reply to this action, to provisionally elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Currently, there is no generic claim encompassing the species. Rather, claim 29 is a Markush type claim subject to a provisional election of species as set forth in MPEP 803.02.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each of SEQ ID NOs 8-135 is a structurally distinct chemical compound. Moreover, as set forth in the PCT International Search and Preliminary Examination Guidelines, the members of a Markush grouping of alternative chemical compounds are deemed to have unity of invention as follows:

Art Unit: 1637

*"Markush Practice"**AI Annex B, Part I(f)*

10.17 Rule 13.2 also governs the situation involving a single claim that defines alternatives (chemical or non-chemical), the so-called "Markush practice." In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, is considered met when the alternatives are of a similar nature.

(a) When the Markush grouping is for alternatives of chemical compounds, they are regarded as being of a similar nature where the following criteria are fulfilled:

(A) all alternatives have a common property or activity, and

(B)(1) a common structure is present, that is, a significant structural element is shared by all of the alternatives, or

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

(b) In paragraph (a)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together.

(c) In paragraph (a)(B)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

(d) The fact that the alternatives of a Markush grouping can be differently classified is not, taken alone, considered to be justification for a finding of a lack of unity of invention.

(e) When dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention should be reconsidered by the examiner. Reconsideration does not necessarily imply that an objection of lack of unity will be raised.

In this case, the only "common property" that can be ascribed to SEQ ID NOs 8-135 is that they can all be used as probes to detect complementary sequences in various HPV genotypes. However, as explained above, the prior art teaches sequences (probes) having this property. Furthermore, the requirements of paragraph (a)(B)(1) and (a)(B)(2) are not satisfied since SEQ ID NOs 8-135, as a group, do not share a common structure, and as explained in paragraph (c) could not be substituted one for the other

Art Unit: 1637

with the expectation that the same intended result would be achieved. This is clear from a reading of Applicant's specification at page 7, e.g., where it is seen that the various SEQ ID NOs are designed to detect and/or identify different HPV types. Hence one could not substitute SEQ ID NO 8 (HPV 6b genotype) for SEQ ID NO 10 (HPV 11 genotype).

Upon election of a species (i.e. one SEQ ID NO from among SEQ ID NOs 8-135), the examiner will search first for that species (assuming Group II was elected). If that species is free of the art, the examiner will proceed to search remaining species until one of the other species is found unpatentable (or until all species are found free of the art). If, however, the elected species is found unpatentable, a further search for the remaining species will not be made. See MPEP 802.02.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1637

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAMUEL WOOLWINE whose telephone number is (571)272-1144. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel Woolwine/  
Examiner, Art Unit 1637